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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CYNTHIA C. BAMDAD and ROBERT C. MUCIC

Appeal 2009-015145
Application 10/016,416
Technology Center 1600

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for performing analyte assays. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The Specification discloses "the use of particles comprising binding ligands and electron transfer moieties (ETMs)" (Spec. 1: 6-7). The Specification discloses that "[u]pon binding of a target analyte, a particle and a reporter composition are associated and transported to an electrode surface. The ETMs are then detected, allowing the presence or absence of the target analyte to be determined" (*id.* at 6-7).

Claims 18, 20-25 and 27 are on appeal. Claim 18 is the only independent claim and reads as follows:

18. A composition comprising:
a) a substrate comprising an array of working electrodes, wherein each electrode comprises a first binding ligand;
b) a plurality of colloids, each comprising:
i) a second binding ligand; and
ii) an electron transfer moiety; and
c) a detector capable of detecting a voltage associated with electron transfer from said electron transfer moiety.

Issue

The Examiner has rejected claims 18, 20, 23-25, and 27 under 35 U.S.C. § 103(a) as being obvious in view of Sigal,[2] Roberts,[3] and Meade.[4] The Examiner has also rejected claim 21 in view of Sigal, Roberts, Meade, and Bamdad;[5] and claim 22 in view of Sigal, Roberts, Meade, and

[2] Sigal et al., US 6,319,670 B1, Nov. 20, 2001
[3] Roberts et al., US 5,958,791, Sept. 28, 1999
[4] Meade et al., US 5,770,369, June 23, 1998
[5] Bamdad et al., US 5,620,850, Apr. 15, 1997

Gerpheide.[6] Since the same issue is dispositive with respect to each rejection, we will address them together.

The Examiner finds that Sigal discloses a composition comprising "microparticles (ie., colloidal gold particles) … having one or more copies of a first assay-ligand … and a plurality of ECL [electrochemiluminescent] moieties immobilized on its surface and … a second assay-ligand immobilized on an electrode" (Ans. 3-4). The Examiner finds that Sigal does not disclose "a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety," as required by the claims (*id.* at 4). The Examiner finds that Meade discloses the required detector (*id.* at 5) and that Roberts discloses the "advantages of fabricating small electrodes in interdigitated arrays" (*id.*).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine Meade's detector with Sigal's assay composition because doing so requires "the simple replacement of one kind of detector … from another kind of detector … since the methods capable of detecting an electron transfer moiety are exchangeable" (*id.* at 5-6).

Appellants contend that one of ordinary skill in the art would not have been motivated to combine Sigal's assay composition with Meade's voltage detector because the combination would be inoperable (Appeal Br. 7-9).

The dispositive issue for all of the rejections is: Does the evidence of record support the Examiner's conclusion that it would have been obvious to combine Sigal's assay composition with Meade's voltage detector?

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[6] Gerpheide et al., US 5,565,658, Oct. 15, 1996

Findings of Fact

1. Sigal discloses assays based on electrochemiluminescence (ECL) "triggered by a voltage imposed on a working electrode at a particular time and in a particular manner. The light produced by the label is measured and indicates the presence or quantity of the analyte." (Sigal, col. 1, ll. 45-50.)

2. Sigal discloses that its assays use "[c]olloidal gold particles having one or more assay ligands immobilized on its outer surface and a plurality of ECL moieties immobilized on its outer surface" (*id.* at col. 2, ll. 55-59).

3. Sigal discloses that its "[a]ssays … are conducted by (a) forming a composition comprising (i) the sample, and one or more microparticles of the invention; (b) incubating said composition to form a complex; (c) causing the complex to bind to an assay-ligand immobilized on an electrode; and (d) conducting an electrochemiluminescence measurement" (*id.* at col. 2, l. 65 - col. 3, l. 5).

4. Sigal discloses that "ECL was measured in electrochemical cells.… Light emitted from the working electrode surface was measured with a photomultiplier tube (PMT). The potential at the working electrode was controlled with a potentiostat." (*Id.* at col. 17, ll. 21-28.)

5. Meade discloses

> the modification of nucleic acids at specific sites with redox active moieties such as transition metal complexes. An electron donor and/or electron acceptor moiety are covalently bound at predetermined positions. The resulting complexes represent a series of new derivatives that are biomolecular templates capable of transferring electrons over very large distances at extremely fast rates. These complexes possess unique structural features which enable the use of an entirely new class of bioconductors and diagnostic probes.

(Meade, col. 5, ll. 24-34.)

6. Meade discloses that "[e]lectron transfer through nucleic acid can be detected in a variety of ways … [including] optical detection, which includes fluorescence, phosphorescence, and refractive index; and electronic detection, including, but not limited to, amperommetry, voltammetry, capacitance and impedence" (*id.* at col. 25, ll. 42-47).

7. Meade discloses that, in one embodiment, "electrochemi-luminescence is used as the basis of the electron transfer detection. With some electron transfer moieties such as $Ru^{2+}(bpy)_3$, direct luminescence accompanies excited state decay. Changes in this property are associated with nucleic acid hybridization and can be monitored with a simple photomultiplier tube arrangement." (*Id.* at col. 26, l. 62 – col. 27, l. 1.)

Analysis

Claim 18 is directed to a composition comprising a substrate comprising an array of working electrodes that comprise a first binding ligand, a plurality of colloids that comprise a second binding ligand and an electron transfer moiety (ETM), and a detector that can detect a voltage associated with electron transfer from the ETM.

The Examiner finds that Sigal does not disclose a detector capable of detecting the voltage associated with electron transfer from an ETM (Ans. 4) but Meade does (*id.* at 5). The Examiner concludes that the combination would have been obvious because it involves "the simple replacement of one kind of detector … from [sic, with?] another kind of detector" and the two detectors "are used for the same purpose (ie., detecting electron transfer of the transition metal complex)" (Ans. 5-6).

Appellants argue that one of skill in the art would not have been motivated to combine Sigal's assay composition with Meade's detector

because Sigal's assay is based on detecting photons, not electrons, and "[a]dding the detector of *Meade* to *Sigal* would result in no signal - the assay would be inoperable, and in fact, changing the operability of *Sigal*, thus 'change the principle of operation'" (Appeal Br. 9).

Appellants' arguments are persuasive that the Examiner has not adequately explained why one of skill in the art would have substituted Meade's electron transfer detector for Sigal's photomultiplier tube. The Examiner responded to Appellants' argument by pointing out that Meade discloses detecting electron transfer by both electrochemiluminescence detection and voltage detection, and that Meade discloses that the electron transfer detection methods are exchangeable (*id.* at 15-17). However, Sigal's assay is based on detecting photons that are generated by electrochemiluminescence (see FFs 1-3), and therefore requires a detector capable of detecting photons, rather than "a *voltage* associated with electron transfer *from said electron transfer moiety*," as required by claim 18 (emphasis added). The Examiner has not adequately explained why a person of ordinary skill in the art would have substituted a voltage detector for a photon detector in an assay based on detecting photons.

In addition, in claim 18, the electron transfer moiety (ETM) is an *electron donor* in an electron transfer process ("voltage associated with electron transfer *from* said electron transfer moiety"). The Examiner has not adequately shown that Sigal's ECL moiety (which the Examiner finds corresponds to the claimed ETM) is an electron donor in an electron transfer process. Thus, the Examiner has not established that substitution of a voltage detector of electron transfer for Sigal's electrochemiluminescence detector would have resulted in a composition comprising a detector capable

of detecting a voltage associated with electron transfer from Sigal's ECL moiety.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that it would have been obvious to combine Sigal's assay composition with Meade's voltage detector.

SUMMARY

We reverse the rejection of claims 18, 20-25 and 27 under 35 U.S.C. § 103(a).

REVERSED

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